IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE HEMISPHERX BIOPHARMA, INC. LITIGATION	:	CIVIL ACTION NO. 09-CV-5262

REPLY MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS PLAINTIFF'S CONSOLIDATED [AMENDED] CLASS ACTION COMPLAINT

Robert L. Hickok
Gay Parks Rainville
Michele C. Zarychta
William A. Liess
PEPPER HAMILTON LLP
3000 Two Logan Square
Eighteenth & Arch Streets
Philadelphia, PA 19103
(215) 981-4000

Attorneys for Defendants
Hemispherx Biopharma, Inc.
William A. Carter, M.D.
David R. Strayer, M.D.

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Defendants Hemispherx Biopharma, Inc. ("Hemispherx" or "the Company"), William A. Carter, M.D., and David R. Strayer, M.D. (collectively "the individual defendants" and, with Hemispherx, "defendants"), by their attorneys, hereby submit this memorandum of law in reply ("Reply Brief") to Lead Plaintiff's Memorandum in Opposition to Defendants' Motion to Dismiss ("plaintiff's Opposition" or "Pl.'s Opp.").

I. INTRODUCTION

In their Opening Brief, defendants provided a chronological history of many of their voluminous public statements regarding the status of the Ampligen® NDA to show that they promptly, fully and repeatedly disclosed before and throughout the putative Class Period the very information plaintiff alleged they had omitted: (a) that the FDA had advised Hemispherx of alleged deficiencies in its Ampligen® NDA; (b) that the FDA had asked Hemispherx for additional information; and (c) that Hemispherx's need to remedy the alleged deficiencies would delay FDA's review of the application. (*See* Defs.' Open. Br. at 5-42, 48-52) (citing Defs.' Exh. , Am. Compl. ¶¶ 4, 5). To illustrate the pervasiveness of these disclosures, defendants have appended to this Reply Brief three timelines: (1) a timeline presenting many, but not all, of defendants' disclosures before and during the putative Class Period regarding the timing of the FDA's decision on the Ampligen® NDA; (2) a timeline presenting many, but not all, of defendants' disclosures regarding Ampligen® safety and efficacy issues, and (3) a cumulative timeline which contains both sets of disclosures.[1]

Defendants in their Opening Brief also showed that their statements of belief or opinion, forward-looking statements and statements of optimism contained in the Amended

[1] These timelines are appended hereto as Exhibits A, B and C. Defendants also have appended as Exhibit D a copy of Hemispherx's July 8, 2008 press release to replace Exhibit 22 to defendants' Opening Brief. Additional exhibits are discussed *infra*.

Complaint were not actionable under the federal securities laws. (*Id.* at 52-68.) They further explained that the Amended Complaint failed to meet the heightened requirements for pleading a strong inference of scienter under the Private Securities Litigation Reform Act of 1995 ("PSLRA") (*Id.* at 69-81.)

Having been presented with the very disclosures the Amended Complaint alleges defendants failed to make, plaintiff now seeks to salvage its pleading by recasting its securities fraud claims into two theories: (1) that defendants ***knew***, ***misrepresented*** and ***concealed*** the FDA's reasons for delaying its decision on the Ampligen® NDA, and (2) that defendants ***knew, misrepresented*** and ***concealed*** that the FDA considered the Ampligen® NDA to be deficient in terms of both safety and efficacy and would not approve it without a third clinical trial. (*See, e.g.*, Pl.'s Opp. Br. at 15.) Yet, plaintiff's new claims lack the most basic ingredient for a securities law violation: ***factual*** information that contradicts defendants' public statements and was known or knowable to them during the putative Class Period. Plaintiff theorizes that defendants somehow had inside information about the FDA's innermost decision-making, but it has alleged no contemporaneous facts in support of these theories. Nowhere in either the Amended Complaint or the Opposition Brief has plaintiff pointed to any communication from the FDA advising defendants of the ***actual*** reasons for the Agency's June-November delay in completing its review of the NDA or providing defendants with advance notice of the Agency's decision.

Plaintiff tries to fill this void with respect to its new "FDA delay" theory by disingenuously asserting that Hemispherx "admitted" in its November 2, 2009 press release that "numerous ongoing FDA inquiries and the required submission of ten new reports were the cause of the delays in the FDA's review of the Ampligen NDA." (Pl.'s Opp. Br. at 14 (emphasis

removed). Yet, defendants have never made any such admission – in that press release or anywhere else. In fact, the FDA has never given Hemispherx a reason for its June -November delay in issuing a decision on the Ampligen® NDA. Plaintiff's FDA delay claim is particularly deficient in that the Amended Complaint contains ***no*** scienter allegations in support of that claim.[2]

Plaintiff also misleadingly argues that courts will not consider a "truth-on-the-market" defense in the context of a motion to dismiss. (Pl.'s Opp. Br. at 6-7, 25.) As explained in Section II.B below, courts in the Third Circuit have consistently and repeatedly recognized that the public disclosure of allegedly omitted information before or during the putative class period renders an alleged misstatement or omission "immaterial or not misleading ***as a matter of law***," and claims based on such misstatements or omissions must be dismissed.

Most egregious is plaintiff's utter disregard for the applicable standard of review for motions to dismiss securities fraud complaints under the PSLRA. Citing inapposite non-securities case law, plaintiff misleadingly argues that defendants' motion to dismiss inappropriately raises factual issues. (Pl.'s Opp. Br. at 23-25.) To the contrary, and as explained at length in defendants' Opening Brief (Defs.' Open. Br. at 46-47), defendants' motion is appropriately based on documents incorporated by reference in the Amended Complaint and matters upon which the Court may properly take judicial notice. Defendants cite and append these documents for the purpose of presenting all of the relevant public disclosures made by defendants during the relevant time period. Indeed, were the Court "to refrain from considering

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[2] *See infra* Section II.A.1

[3] *Wallace v. Sys. & Computer Tech. Corp.*, No. 95-CV-6303, 1997 U.S. Dist. LEXIS 14677, at *44 (E.D. Pa. Sept. 23, 1997) (emphasis added

these documents, complaints that allege fraud due to material omissions during a class period would survive a motion to dismiss even though they would be doomed to failure because the alleged omissions were actually disclosed to the market. Foreclosing resort to such documents might lead to complaints filed solely to extract nuisance settlements."[4] Moreover, it is well-settled that the Court need not accept as true a complaint's factual allegations that contradict "documents deemed to be part of the complaint, or materials amenable to judicial notice."[5]

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In sum, plaintiff's new claims, like its old claims, are bereft of any factual allegations and, instead, are based on nothing more than impermissible speculation and fraud-by-hindsight. The purpose of the Private Securities Litigation Reform Act of 1995 ("PSLRA") is to prevent such speculative litigation by imposing a gatekeeping role on district courts at the motion to dismiss stage and mandating that they dismiss all securities fraud complaints that fail to meet the PSLRA's stringent pleading requirements. Where, as here, a complaint fails to comply with the PSLRA's heightened pleading requirements, "the court ***shall***, on the motion of any defendant, dismiss the complaint . . . ") 15 U.S.C. § 78u-4(b)(3)(A) (2007) (emphasis added).

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[4] *Wallace v. Sys. & Computer Tech. Corp*, No. 95-CV-6303, 1997 U.S. Dist. LEXIS 14677, at *22-*23 (E.D. Pa. Sept. 23, 1997) (citation and internal quotation marks omitted).

[5] *In re Yukos Oil Co. Sec. Litig.*, No. 04-CV-5243, 2006 U.S. Dist. LEXIS 78067, at *35 (S.D.N.Y. Oct. 25, 2006) ("[t]he Court need not accept as true any allegations that are contradicted by documents deemed to be part of the complaint, or materials amenable to judicial notice); *accord St. Matthew's Baptist Church v. Wachovia Bank Nat'l Assoc.*, No. 04-4540 (FLW), 2005 U.S. Dist. LEXIS 46607, *7 (D.N.J. May 18, 2005) ("To the extent that Plaintiff's allegations are contradicted by the documents attached to the Complaint upon which its claims are based, the Court need not accept such allegations as true."); *In re Bausch & Lomb, Inc. Secs. Litig.*, 592 F. Supp. 2d 323, 350 & n.30 (W.D.N.Y. 2008) (dismissing Rule 10b-5 case in which plaintiffs alleged that Bausch & Lomb's statements regarding the safety of its MoistureLoc product were false and misleading in part because the "Court need not accept as true any allegations that are contradicted by documents deemed to be part of the complaint, or materials amendable to judicial notice" and plaintiffs' allegations in the Complaint regarding defendant's omisssions were contradicted by "controlling documents"); *Rapoport v. Asia Elecs. Holding Co.*, 88 F. Supp. 2d 179, 184 (S.D.N.Y. 2000) ("This Court finds that the documents contradict Plaintiffs' allegations [in the amended complaint] and, therefore, this Court must grant Defendants' motion to dismiss.").

II. ARGUMENT

A. Plaintiff Has Failed To Allege Any Facts Showing That Either (1) The FDA's Reasons For Delaying Its Decision On The Ampligen® NDA After May 2009 Or (2) The Substance Of That Decision Was Known Or Knowable To Defendants During The Putative Class Period

In order for the Amended Complaint to survive dismissal, plaintiff must "allege facts giving rise to a strong inference of either reckless or conscious behavior." *Institutional Investors Group v. Avaya, Inc.*, 564 F.3d 242, 267 (3d Cir. 2009) (internal quotation marks and footnote omitted). Here, plaintiff must therefore adequately allege facts giving rise to a strong inference that defendants knew or must have known during the putative Class Period (a) the FDA's reasons for delaying its decision on the Ampligen® NDA after May 2009 and (b) that the FDA would not approve the NDA. For the reasons discussed below, and at length in defendants' Opening Brief, plaintiff has utterly failed to satisfy this requirement. The Amended Complaint, therefore, must be dismissed.

1. Plaintiff Has Made No Scienter Allegations In Support Of Its Theory That Defendants Knew And Concealed The FDA's Reasons For Delaying Its Decision On The Ampligen® NDA After May 2009

The Amended Complaint contains ***no*** allegations of fact in support of plaintiff's speculative theory regarding the reasons for the FDA's delay in reaching a decision on the Ampligen® NDA. In its Opposition Brief, plaintiff baldly states that the "true reasons for the FDA delays" were "that the Company had numerous outstanding issues to which it had to respond." (Pl. Opp. Br. at 58.) But plaintiff does not, and cannot, point to any factual allegations in the Amended Complaint that could substantiate these alleged "true reasons" for the delay. Even if this speculative assertion appeared in the Amended Complaint, which is unclear, it was certainly not pleaded with particularity as required by the PSLRA, and thus cannot support an

inference of scienter. To the extent this "delay" argument could be construed as an additional claim, that claim must accordingly be dismissed.

2. Plaintiff's Allegations Regarding The Individual Defendants' Corporate Positions and Familiarity With Ampligen® Cannot Support An Inference Of Scienter Because The Allegations Have No Bearing On Defendants' Knowledge About Internal FDA Processes

In its Opposition Brief, plaintiff reiterates certain allegations suggesting that Drs. Carter and Strayer were knowledgeable about Ampligen®, and Hemispherx's conduct with regard to its development of the drug. Plaintiff points to allegations in the Amended Complaint that defendants Carter and Strayer held "high-ranking positions" at Hemispherx, and allegations that Ampligen® was a "core product" of Hemispherx. (Pl. Opp. Br. at 56-58.) Similarly, plaintiff points to a purported statement by an alleged former Hemispherx employee suggesting that Dr. Carter controlled outgoing communications regarding Ampligen®. (Pl. Opp. Br. at 61.) Plaintiff asserts that, because of defendants' corporate roles[6] and familiarity with Ampligen®, scienter may thereby be imputed as to them. (Pl.'s Opp. Br. at 58.)

Courts in this circuit have consistently refused to impute to corporate officers any knowledge of falsity on the basis of generalized allegations regarding a defendant's position, or the importance of a particular product to a business. *E.g. In re Alpharma Inc. Sec. Litig.*, 372

[6] Plaintiff makes an additional "corporate role" argument with regard to Dr. Carter by arguing that the FDA "historically communicated directly with him," by reference to warning letters sent to him by the FDA in 1998 and 2000. (Pl. Opp. Br. at 61-62.) While this argument should have no bearing on the scienter analysis for the reasons discussed above and in defendants' Opening Brief, (Defs. Open. Br. at 77-78), they should be entirely disregarded for an independent reason. These allegations are substantially outside of the Class Period, and involve alleged facts that have no bearing on the Ampligen® NDA at issue in the present matter. While the U.S. Court of Appeals for the Third Circuit considered pre-class period statistical data in *In re Merck & Co. Securities Litigation*, 432 F.3d 271 (3d Cir. 2005), it did so only after reasoning that the data in question were relevant to showing that statements at issue were misleading. *Id.* at 272. Here, plaintiff's allegations with regard to the FDA letters of 1998 and 2000 bear no relation to the Ampligen® NDA that was filed in October 2007, and cannot reasonably be deemed to be relevant to the question of whether defendants knew or must have known that the Ampligen® NDA would ultimately not be approved

F.3d 137, 149 (3d Cir. 2004) ("generalized imputations of knowledge do not satisfy the scienter requirement regardless of the defendants' positions within the company.'" (internal quotation marks omitted)); *In re Stonepath Group, Inc. Sec. Litig.*, No. 04-4515, 2006 U.S. Dist. LEXIS 15808, at *36 (E.D. Pa. Apr. 3, 2006);[7] *In re Bio-Tech. Gen. Corp. Sec. Litig.*, 380 F. Supp. 2d 574, 596-97 (D.N.J. 2005) (refusing to impute knowledge of sales data to corporate officials based on the mere allegation that the product at issue was the corporation's "premier product"). (*See* Defs. Open. Br. at 74.) Furthermore, the alleged statement offered by plaintiff from a purported former employee lacks any relevant detail and, in any event, identifies only commendable behavior on the part of Dr. Carter.[8] (*See* Defs. Open. Br. at 75.)

[7] Plaintiff argues that *Stonepath* "reinforce[s] that courts may impute knowledge of a key product to high-ranking officials." (Pl. Opp. Br. at 56 n.34.) The court in *Stonepath* acknowledged that allegations regarding core activities had been relevant to other courts for imputing knowledge "in some circumstances," but also noted that in each of the cases cited, "the Courts plainly did *not* impute knowledge absent particularized allegations showing that defendants had ample reason to know the falsity of their statements." *Stonepath*, 2006 U.S. Dist. LEXIS 15808 at *34. The court, citing *Advanta* further noted that "caution" in imputing knowledge to corporate officials, "is not simply prudent, it is required." *Id.* The court in *Stonepath* ultimately held that it could not impute knowledge to the corporate officials at issue, and this case therefore cannot "reinforce" the liberal imputation rule that plaintiff would have this Court apply.

[8] In its Opposition Brief, plaintiff misconstrues prior cases to stand for a loose rule that "statements of confidential witnesses are valuable, and courts often recognize that they can create a strong inference of scienter." (Pl. Opp. Br. at 61.) However, the Third Circuit has made clear that the scrutiny of alleged statements by confidential witnesses under the PSLRA is rigorous:

> The PSLRA imposes a particularity requirement on all allegations, whether they are offered in support of a statement's falsity or of a defendant's scienter. 15 U.S.C. § 78u-4(b)(1), (b)(2). In the case of confidential witness allegations, we apply that requirement by evaluating the "detail provided by the confidential sources, the sources' basis of knowledge, the reliability of the sources, the corroborative nature of other facts alleged, including from other sources, the coherence and plausibility of the allegations, and similar indicia." [*Cal. Pub. Employees' Ret. Sys. v. Chubb Corp.*, 394 F.3d 126, 147 (3d Cir. 2004)]. If anonymous source allegations are found wanting with respect to these criteria, then we must discount them steeply. This is consistent with *Tellabs*'s teaching that "omissions and ambiguities count against inferring scienter" under the PSLRA's particularity requirements. *Tellabs*, 127 S. Ct. at 2511.

Avaya, 564 F.3d at 263. The alleged two-sentence statement by a former employee offered by plaintiff (Am. Compl. ¶ 86), as discussed above, adds no plausible value the scienter analysis, even if the allegation was deemed to satisfy the *Chubb* test. Yet plaintiff offers no details regarding the basis for the alleged employee's knowledge except that the employee worked closely with Dr. Carter in an administrative capacity. (*Id.*) Moreover, the substance of the alleged statement, that Dr. Carter controlled information flow, is not corroborated elsewhere in the Amended Complaint, and plaintiff provides no indicia of reliability. It is clear that plaintiff's meager effort to include a

(continued...)

Yet plaintiff's "corporate role" and "core product" arguments in its Opposition Brief highlight a more glaring defect of the Amended Complaint. Defendants' knowledge of Ampligen®, and their involvement in Hemispherx's business, simply have no bearing on plaintiff's fraud theories. The Amended Complaint cannot survive dismissal absent a strong inference that, during the Class Period, defendants knew or must have known the reasons for the FDA's June-November delay in rendering a decision on the Ampligen® NDA or that the FDA was not going to approve the NDA without a third clinical trial. The issue *is not* what defendants knew or must have known about Ampligen® or the internal affairs of Hemispherx. The issue is what defendants knew or must have known *about the internal affairs of the FDA*. Leaving aside the legal inadequacy of their arguments, and assuming, *arguendo*, that Drs. Carter and Strayer knew everything that Hemispherx did with regard to Ampligen®, these allegations would still shed no light on defendants' knowledge as to how the FDA would ultimately rule on the Ampligen® NDA.

Every case to which plaintiff points involved questions of whether a person making statements on behalf of a corporation was aware of conduct or circumstances *within the same corporation*. *Avaya*, 564 F.3d at 269-70 (whether CFO of a corporation was aware of causes for major reduction in that corporation's earnings); *Makor Issues & Rights Ltd. v. Tellabs, Inc.*, 513 F.3d 702, 707-09 (7th Cir. 2008) (whether corporate officials were aware that sales of a particular product of that corporation were declining); *In re RAIT Fin. Trust Sec. Litig.*, No. 07-03148, 2008 U.S. Dist. LEXIS 103549 at 45-50 (E.D. Pa. Dec. 22, 2008) (whether

(continued...)

statement by a former employee fails the *Chubb* standard, and that the resulting allegation must be found wanting and, at a minimum, be steeply discounted.

principals of a trust were aware of credit risks assumed by that trust).[9] But here, the relevant question is whether the individual defendants knew or must have known in advance that a *third party*, namely the FDA, would not approve the Ampligen® NDA. No degree of familiarity with either Hemispherx generally, or Ampligen® specifically, could enhance either individual defendant's knowledge of the FDA's internal progress in its review of the Ampligen® NDA.

For these reasons, and the reasons discussed at length in defendants' Opening Brief, plaintiff's "corporate role" and "core product" allegations, including the alleged statement by a former employee, cannot strengthen an inference that defendants knew or must have known that the FDA would not approve the Ampligen® NDA.

3. Plaintiff Fails To Allege Any Communication By The FDA Indicating That The NDA Would Not Be Approved Or A Statement By Defendants Indicating Knowledge Thereof

Again, in order for the Amended Complaint to survive dismissal, plaintiff must have alleged facts giving rise to a strong inference that, during the Class Period, defendants knew or must have known that the FDA would not approve the Ampligen® NDA. Since knowledge of internal Hemispherx conduct is irrelevant, it is logical to next consider whether plaintiff has alleged the existence of any communications by the FDA to Hemispherx, prior to the Complete Response Letter, that would have informed defendants that that the NDA would not be approved. Plaintiff has plainly failed to do so. Neither in the Amended Complaint, nor in its Opposition

[9] The remaining cases cited by plaintiff on this point are: *In re Tel-Save Sec. Litig.*, No. 98-CV-3145, 1999 U.S. Dist. LEXIS 16800 (E.D. Pa. Oct. 19, 1999) (whether CEO of a company had knowledge of that company's transactions); *In re Aetna Inc. Sec. Litig.*, 34 F. Supp. 2d 935, 953 (E.D. Pa. 1999) (whether officers of a corporation were aware of issues relating to a merger of that corporation); *In re Campbell Soup Co. Sec. Litig.*, 145 F. Supp. 2d 574, 599 (D.N.J. 2001) (whether officers of a corporation were aware of reservations about corporate policies raised during internal meetings); *In re Viropharma Inc. Sec. Litig.*, 2003 U.S. Dist. LEXIS 5623, at *31 (E.D. Pa. Apr. 3, 2003) (whether corporate officers were aware of results of testing on that corporation's product); *In re Loewen Group Inc. Sec. Litig.*, No. 98-6740, 2004 U.S. Dist. LEXIS 16601, at *67 (E.D. Pa. Aug. 18, 2004) (whether CFO of a corporation was aware of accounting practices of that corporation); *In re Vicuron Pharms., Inc. Sec. Litig.*, No. 04-2627, 2005 U.S. Dist. LEXIS 15613, at *25-26 (E.D. Pa. July 1, 2005) (whether officials within a corporation were aware of certain characteristics of that corporation's product).

Brief, does plaintiff point to a single communication by the FDA to Hemispherx that would have alerted defendants in advance that the NDA would not be approved. Apparently aware of this glaring defect, plaintiff presents other strained and contrived allegations in an effort to craft an inference that defendants knew or must have known that the NDA would not be approved. These allegations are either legally insufficient or factually irrational.

(a) Plaintiff's Allegations Regarding General FDA Publications And The Requested Carcinogenicity Waiver Fail To Meet the Particularity Requirements Of The PSLRA And Should Be Disregarded

Lacking any specific allegation that the FDA provided advanced notice to defendants that the NDA would not be approved, plaintiff instead relies on general FDA publications regarding the NDA process as an apparent substitute. (Pl.'s Opp. Br. at 60.) Plaintiff points to normative statements within the publications discussing, in general terms, the desired timeliness of communications between the FDA and an NDA applicant. (*Id.*) Plaintiff argues that, on the mere basis of these generalized statements, "it would strain credulity to believe that, for example, the FDA remained silent" on Hemispherx's request for a carcinogenicity testing exemption. (*Id.* at 60.)

Plaintiff likewise fails to make any specific allegations identifying a communication from the FDA, prior to the Complete Response Letter, by which defendants would have learned that the requested waiver of carcinogenicity studies would be denied. In the absence of any such allegation, plaintiff merely argues that "it is reasonable to infer that Defendants knew – or were reckless in not knowing – that such a request would be denied, considering their vast experience, the numerous conversations they had with the FDA and the fact that the FDA never *approved* their request." (Pl. Opp. Br. at 60.)

In both instances, plaintiff seeks to rely on impermissible speculation to create an inference that the FDA informed defendants in advance that the NDA would not be approved as filed. These generalized allegations lack the requisite "particularity" for the pleading of scienter under 15 U.S.C. § 78u-4(b)(2). "Inferring scienter in these circumstances would impermissibly provide [plaintiff] the benefit [of] inferences flowing from vague or unspecific allegations. In other words, because of the [Amended] [C]omplaint's omissions, it fails to set out the 'who, what, when, where and how' of the events at issue." *Key Equity Investors Inc. v. Sel-Leb Mktg.*, 246 Fed. Appx. 780, 786 (3d Cir. 2007) (internal citations and quotation marks omitted). Since the allegations regarding FDA publications and the requested carcinogenicity waiver fail to meet the particularity requirements of the PSLRA, they should be entirely disregarded by this Court.

(b) Allegations Of Statements By Defendants Comparing The Ampligen® NDA To the Lyrica NDA Cannot Plausibly Support An Inference That Defendants Knew A Third Trial Would Be Required For Approval Because Lyrica Was Approved With Only Two Trials

Lacking any particularized allegations that the FDA gave defendants notice that the Ampligen® NDA would not be approved as filed, plaintiff attempts to build an inference of knowledge based on certain statements by Dr. Carter regarding Lyrica, a drug developed by Pfizer for the treatment of Fibromyalgia. Plaintiff alleges that, in an April 9, 2008 conference call, Dr. Carter called fibromyalgia the "sister disease of chronic fatigue," and that Dr. Carter was encouraged that Pfizer's launch of Lyrica "seem[ed] to be going tremendously well." (Am. Compl. ¶ 90.) Plaintiff further alleges that, in a December 3, 2009 conference call, made after the FDA informed Hermispherx that a third trial would be required, Dr. Carter stated that "[a] third trial is not unexpected," in part because the FDA required a third clinical trial for Lyrica. (*Id.* at 41-42.) Plaintiff argues that these statements support a strong inference that defendants

knew that the Ampligen® NDA would not be approved without a third clinical trial. (Pl. Opp. Br. 59.)

These allegations cannot possibly support an inference of scienter because the third clinical trial required by the FDA when it approved Lyrica was to be conducted ***post***-approval -- in other words, ***after*** the drug received clearance to be marketed for a fibromyalgia indication, with only two clinical trials. (*See* Exh. 111, U.S. Food and Drug Administration, June 21, 2007 Press Release, FDA Approves First Drug for Treating Fibromyalgia *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2007/ucm108936.htm.) Indeed, FDA "approved Lyrica" for the treatment of fibromyalgia, in part on the basis of only "[t]wo double-blind, controlled clinical trials." (*Id.*) Thus, Dr. Carter's statements regarding Lyrica cannot support a plausible inference that he ***knew*** Ampligen® would not be approved on the basis of two clinical trials. To the contrary, the Lyrica regulatory history supports an inference that approval of Ampligen® on the basis of two clinical trials was a reasonable expectation.

4. Plaintiff's Motive Allegations Cannot Independently Establish An Inference Of Scienter, And Do Not Otherwise Support An Inference of Scienter Because They Do Not Describe Concrete And Personal Benefits

Although plaintiff admits that *Avaya* foreclosed motive and opportunity as an independent means to establish scienter (Pl. Opp. Br. at 62), the organization of its Opposition Brief suggests that plaintiff does not fully understand the effect of the decision. In one heading, plaintiff asserts that "The Complaint Alleges Conscious Misbehavior and/or Recklessness." (*Id.* at 55.) Yet, in a subsequent and co-equal heading, plaintiff asserts that "The Complaint Alleges That Defendants Had Motive and Opportunity to Commit Securities Fraud." (*Id.* at 62.) *Avaya* makes clear that "allegations of motive and opportunity are not entitled to a special, independent

status." *Id.* at 277. The sole question with regard to scienter under the PSLRA is whether a plaintiff has "alleged facts giving rise to a strong inference of either reckless or conscious behavior." *Id.* at 267 (internal quotation marks and footnote omitted). Thus, plaintiff's allegations regarding motive may only bear on the scienter analysis to the extent they support an inference that defendants either knew or must have known that the alleged statements at issue were false or misleading.

All of plaintiff's motive allegations either assert that the individual defendants were motivated to secure performance bonuses (Am. Compl. ¶¶ 104-05) or to artificially inflate Hemispherx's stock price, whether to raise funds or for Dr. Carter to avoid making a personal loan to the Company. (Am. Compl. ¶¶ 83-85). As discussed in defendants' Opening Brief, alleged motives to secure performance-based incentives are legally inadequate to support an inference of scienter. (Defs. Open. Br. at 80-81.) Plaintiff does not, and cannot, offer an argument in reply, but merely reiterates the alleged amounts of the bonuses awarded to Drs. Carter and Strayer. (Pl. Opp. Br. at 66.) It should accordingly be clear that plaintiff's allegations relating to performance bonuses should have no bearing on the scienter analysis.

As for the alleged motives for inflating Hemispherx's stock price, plaintiff strains to have this Court rely on cases that plainly do not control.[10] Despite plaintiff's inaccurate

[10] *See* Pl. Opp. Br. at 65-66. Of the seven cases on which plaintiff would have this Court rely, seven predate the critical Supreme Court *Tellabs* decision, and are from other circuits. *Southland Sec. Corp. v. InSpire Ins. Solutions, Inc.*, 365 F.3d 353 (5th Cir. 2004); *In re Vantive Corp. Sec. Litig.*, 283 F.3d 1079 (9th Cir. 2002); *In re MicroStrategy*, 115 F. Supp. 2d 620 (E.D. Va. 2000); *In re Ibis Tech. Sec. Litig.*, 422 F. Supp. 2d 294 (D. Mass. 2006); *In re Am. Bank. Note Holographics Sec. Litig.*, 93 F. Supp. 2d 424 (S.D.N.Y. 2000). As for *Makor Issues & Rights, LTD. v. Tellabs Inc.*, 513 F.3d 702 (7th Cir 2008), the very case remanded by the Supreme Court, plaintiff contends that "the Seventh Circuit explained that a motive to benefit the corporation can be both compelling and cogent." (Pl. Opp. Br. at 65.) No such simplistic statement by the Seventh Circuit can be distilled from the opinion. Judge Posner did not, as plaintiff suggests, leap to a strong inference of scienter on a allegation that corporate officials were motivated to benefit the corporation, but carefully weighed inferences drawn from myriad factual allegations, including statements from 26 alleged confidential sources. *Id.* at 706-12. The sole case relied on by plaintiff from within the Third Circuit, *In re Centocor, Inc. Sec. Litig. III*, No. 98-260, 1999 U.S. Dist. LEXIS 1224

(continued...)

efforts to distinguish the controlling case of *Avaya*,[11] the motive allegations regarding stock price must be reviewed under the settled standard recently reiterated by the Court of Appeals for the Third Circuit:

> "[M]otives that are generally possessed by most corporate directors and officers do not suffice; instead, plaintiffs must assert a concrete and personal benefit to the individual defendants resulting from [the alleged] fraud" . . . . Corporate officers always have an incentive to improve the lot of their companies, but this is not, absent unusual circumstances, a motive to commit fraud.

Avaya, 564 F.3d at 278-79 (quoting *GSC Partners CDO Fund v. Washington*, 368 F.3d 228, 237 (3d Cir. 2004)). As defendants discussed in their Opening Brief, an alleged motive to enhance a company's stock price "surely is the quintessential motive 'generally possessed by most corporate directors and officers,'" and thus cannot support an inference of scienter in this circuit.[12] *In re Discovery Labs. Sec. Litig.*, No. 06-1820, 2006 U.S. Dist. LEXIS 79823, at *44 (E.D. Pa. Mar. 15, 2007) (citing *GSC Partners*, 368 F.3d at 237). (*See* Defs. Open. Br. at 79.)

(Continued . . .)

(E.D. Pa. Dec. 1, 1998), is a terse, unpublished opinion that predates *Tellabs*, and should be read with caution in light of *Avaya*.

[11] Plaintiff argues that *Avaya* is "inapposite" because the case involved a "credit facility that was not tied to the price of defendant corporation's stock." (Pl. Opp. Br. at 65 n.36.) Whether or not the distinction would be of any relevance if true, plaintiff's characterization of the case is plainly wrong. All of the relevant analysis by the court was with regard to the "[s]hareholders alleg[ations] that defendants were 'further motivated' to inflate Avaya's stock in order to" to repurchase certain notes and secure a revolving credit facility – efforts that were plainly affected by share value. *Avaya*, 564 F. 3d at 277. Likewise, plaintiff's effort to distinguish *In re Discovery Labs. Sec. Litig.*, No. 06-1820, 2006 U.S. Dist. LEXIS 79823 (E.D. Pa. Nov. 1, 2006), on the questionable basis that the equity financing agreements sought "were not alleged to be necessary for the very survival of the Company," should be viewed with skepticism. (Pl. Opp. Br. at 65 n.36.)

[12] To the extent plaintiff's stock price allegations relate specifically to Hemispherx's efforts to raise capital through stock offerings, it is also helpful to note that the Class Period offerings alleged by plaintiffs were via stock purchase agreements with sophisticated institutional investors, which investors would rationally be expected to conduct independent investigations into the value of Hemispherx. (Ex. 1, Am. Compl. ¶¶ 84-85.) None of the Class Period offerings alleged by plaintiff's were public sales.

Plaintiff attempts to skirt the application of this rule by arguing that the existence of a Standby Financing Agreement between Hemispherx and Dr. Strayer personalizes the share price motive as to him. (Pl. Op. Br. at 63.) The gravamen of this argument remains that Dr. Carter was motivated to maintain a high share price, and no inference of scienter can be drawn from this "quintessential motive" common to most corporate officers. Even assuming, *arguendo*, that this allegation is sufficiently concrete and personal under *Avaya*, Dr. Carter's interests were at all times aligned with the best interests of the shareholders, whether or not he executed a personal loan under the Standby Financing Agreement, due to his extensive share holdings, including shares given to him in consideration for entering the Agreement. (Defs. Open Br. at 79-80.)

Moreover, to the extent that plaintiff alleges that Dr. Carter was uniquely motivated to temporarily maintain a high share to avoid triggering a personal loan during the life of the Agreement (Pl. Opp. Br. at 63-64), the terms of the Agreement demonstrate that no rational inference of scienter can be drawn from any such allegations. The Standby Financing Agreement provided that Dr. Carter would be obligated to provide a loan in the event that sufficient financing could not be secured "after December 1, 2009 and prior to June 30, 2010." (Exh. 8, 2008 Form 10-K at 42.) Plaintiff's theory that Dr. Carter attempted to hide the truth of the Ampligen® NDA long enough to escape the loan window is irrational, if not preposterous. (Pl. Opp. Br. at 64.) The loan window did not *start* until the day the Complete Response Letter was actually issued by the NDA, and it is inconceivable that Dr. Carter could have expected to "hide" the allegedly known inadequacy of the NDA from the public for another seven months. To the extent Dr. Carter might have expected the FDA to take so long to issue its decision, this

expectation would further undercut plaintiff's speculative premise that Dr. Carter was keenly aware of the FDA's internal processes with regard to the Ampligen® NDA.

For these reasons, and the reasons discussed by defendants in their Opening Brief, plaintiff's allegations of motive and opportunity cannot support an inference of scienter.

5. The Amended Complaint, Taken As A Whole, Fails To Allege Facts Giving Rise To A Strong Inference Of Scienter, And It Must Accordingly Be Dismissed

Plaintiff correctly notes that, under *Tellabs* and *Avaya*, this Court must look to the Amended Complaint as a whole and determine "whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter.'" *Avaya*, 564 F.3d at 267-68 (quoting *Tellabs*, 551 U.S. at 322-23, 24). This Court must weigh competing inferences drawn from those allegations, and the "complaint will survive . . . only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs*, 551 U.S. at 324. Plaintiff has failed to satisfy this standard, and the Amended Complaint must be dismissed on this independent and sufficient ground.

The central question with regard to scienter is whether defendants knew or must have known, prior to the Complete Response Letter, that the FDA was not going to approve the Ampligen® NDA as it was filed. Plaintiff's allegations that Drs. Carter and Strayer were intimately aware of Hemispherx's activities surrounding Ampligen®, whether by virtue of their corporate roles or the importance of the drug, are irrelevant to the operative question of what defendants knew about internal FDA activities. Plaintiffs have also failed to allege the existence of any relevant communication by the FDA, and have failed to allege with particularity any fact from which it could reasonably be inferred that defendants knew or must have known in advance that the NDA would not be approved. In fact, Dr. Carter's statements comparing the Ampligen® NDA with the Lyrica approval process support the opposite inference. Furthermore, plaintiff's

motive allegations regarding stock price and performance-based bonuses are common to corporate officers generally, and are inadequate to support an inference of scienter.

On the other hand, a strong inference can readily be drawn from the Amended Complaint and the entire body of exhibits that defendants operated at all times in the best interests of Hemispherx and its shareholders, and readily communicated all positive and negative news regarding Ampligen® to the public. Lacking a single particularized allegation suggesting that defendants knew or must have known in advance that the Ampligen® would not be approved, no reasonable person could draw an inference in accord with plaintiff's fanciful theory that defendants filed the NDA knowing that it would fail. In short, plaintiff "ha[s] not alleged anything to negate the idea that defendants were attempting to develop a drug they thought beneficial and were so describing it to the public." *In re AstraZeneca Sec. Litig.*, 559 F. Supp. 2d 453, 471 (S.D.N.Y. 2008). This nonculpable explanation for the facts alleged is the most compelling inference, and the Amended Complaint should accordingly be dismissed.

B. Contrary To Plaintiff's Assertions, Courts In This Circuit *Do* Dismiss Securities Class Action Complaints Where, As Here, A Defendant Disclosed The Allegedly Concealed Information Before Or During The Putative Class Period

1. To Proceed Under A Fraud-On-The-Market Theory, Plaintiff Must, And Does, Allege That Hemispherx's Stock Price Reflected Information From *All* Publicly Available Sources

To avoid the burden of proving actual reliance on defendants' alleged misrepresentations, a plaintiff asserting a Rule 10b-5 claim will allege that he is entitled to a rebuttable presumption of reliance under the "fraud-on-the-market" theory adopted by the Supreme Court in *Basic Inc. v. Levinson*, 485 U.S. 224, 250 (1988). This theory is based on the efficient market hypothesis, which provides that, "in an open and developed securities market, the price of a company's stock is determined by the available material information regarding the

company and its business." *Id.* at 241-42. Accordingly, "[a]n investor who buys or sells stock at the price set by the market does so in reliance on the integrity of that price." *Id.* at 247. In essence, "[t]he market is acting as the unpaid agent of the investor, informing him that given all the information available to it, the value of the stock is worth the market price." *Id.* at 244. "Because most publicly available information is reflected in market price, an investor's reliance on any public material misrepresentations, therefore, may be presumed for purposes of a Rule 10b-5 action." *Id.*

Under the fraud-on-the-market doctrine, a "plaintiff need not show that he actually knew of the communication that contained the misrepresentation or omission." *Winer Family Trust v. Queen*, No. 03-4318, 2004 U.S. Dist. LEXIS 19244, at *9 n.3 (E.D. Pa. Sept. 24, 2004) (citing *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1419 n.8 (3d Cir. 1997)), *aff'd on other grounds*, 503 F.3d 319 (3d Cir. 2007). Thus, here, plaintiff specifically alleges that "[t]he market for Hemispherx common stock was open, well-developed and efficient at all relevant times" (Defs.' Exh. 1, Am. Compl. ¶ 116), and that the market "promptly digested current information regarding Hemispherx from ***all*** publicly available sources and reflected such information in Hemispherx's stock prices" (*id.* ¶ 133 (emphasis added)).

2. Under The Truth-On-The-Market Theory, An Alleged Misstatement Or Omission Is Immaterial As A Matter Of Law If The Information Already Has Been Disclosed To The Market

Courts in this Circuit have long recognized that an "essential corollary" to the "fraud-on-the-market" theory is "a 'truth on the market' defense recognizing that a statement is materially misleading ***only*** if the allegedly undisclosed facts have not already entered the market." *Wallace v. Sys. & Computer Tech. Corp*, No. 95-CV-6303, 1997 U.S. Dist. LEXIS

14677, at *42 (E.D. Pa. Sept. 23, 1997) (emphasis added) (citation omitted). As the court in *Wallace* explained: "If the market has become aware of the allegedly concealed information, the facts allegedly omitted by the defendant would already be reflected in the stock's price and the market would not be misled." *Id.* at *42-*43. Thus, public disclosure of the allegedly omitted information before or during the putative class period renders the defendant's alleged misstatement or omission "immaterial or not misleading ***as a matter of law***." *Id.* at *44 (emphasis added).

Citing inapposite case law from outside the Third Circuit, plaintiff makes the false assertion that defendants "are not permitted to assert the truth-on-the-market defense at the motion to dismiss phase because such an inquiry is highly-fact intensive and therefore only appropriate for a fact-finder." (Pl.'s Opp. Br. at 25; *see id.* at 6-7.) Contrary to plaintiff's unabashed misstatement of the law of ***this*** Circuit, courts here have consistently and repeatedly recognized that "[a] truth on the market defense ***can*** . . . be granted on a motion to dismiss where the company's SEC filings or other documents disclose the very information necessary to make their public statements not misleading." *Wallace*, 1997 U.S. Dist. LEXIS 14677, at *13 (dismissing claims on truth-on-the-market grounds and acknowledging that SEC filings and other company documents would transmit information "with a degree of intensity and credibility sufficient to effectively counterbalance any misleading impression created by the defendant's statements"); *accord In re Discovery Labs Sec. Litig.*, No. 06-1820, 2006 U.S. Dist. LEXIS 79823, at *34 (E.D. Pa. Nov. 1, 2006) (granting motion to dismiss on, *e.g.*, truth-on-the-market grounds; recognizing that a "prior public disclosure negates a finding that material information was withheld"); *Winer Family Trust v. Queen*, No. 03-4318, 2004 U.S. Dist. LEXIS 19244, at *37, *40 (E.D. Pa. Sept. 24, 2004) (holding, *e.g.*, that March 29-May 22, 2002 statements "were

not misleading because the allegedly undisclosed facts were otherwise transmitted to the market in a timely manner" and information allegedly omitted from July 11, 2002 press release "had already been transmitted to the public"), *aff'd on other grounds*, 503 F.3d 319 (3d Cir. 2007).

For these reasons and the grounds discussed at length in Section IV.A of defendants' Opening Brief, and as illustrated in the appended timelines, the Amended Complaint fails to plead a misstatement or omission of material fact because defendants disclosed before or during the putative Class Period the allegedly omitted information regarding the status of the Ampligen® NDA.[13]

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[13] In its Opposition Brief, plaintiff argues that the Court should not consider defendants' Exhibit 94, which is a transcription of Michael Vlaicu's May 29, 2009 interview of Dr. Carter, because the website where the interview was originally posted is now "defunct." (Pl.'s Opp. Br. at 39 n.25.) Once again, plaintiff misstates the applicable legal standard the Court must apply when considering documents that contain a defendant's public disclosures. As explained above, the relevant question under the truth on the market doctrine is whether the allegedly omitted information was publicly available during (or before) the putative class period, ***not*** whether the media that published the information still exist ***after*** the close of the Class Period. As plaintiff itself has alleged, the market for Hemispherx's stock "***promptly*** digested current information regarding Hemispherx from all publicly available sources and reflected such information in Hemispherx's stock prices" (Am. Compl. ¶ 133 (emphasis added).) Thus, once the audio recording of the May 29 interview was posted on StocksHaven.com, the market "promptly" absorbed the information disclosed by Dr. Carter during that interview.

Appended hereto as Exhibit 119 is a compact disc containing the audio recordings of Mr. Vlaicu's May 15 and May 29, 2009 interviews of Dr. Carter. (Transcripts of the May 15 and May 29 interviews are appended to defendants' Opening Brief as Exhibits 93 and 94, respectively.) In advance of each interview, Mr. Vlaicu announced that he would be conducting them by, *inter alia*, posting information on Google's financial message board for Hemispherx. (*See* Exh. 113, Posting of Michael Vlaicu of www.StocksHaven.com to http://finance.google.com/group/google.finance.660636/, StocksHaven Investments set to CC HEB Chairman & CEO Dr. Carter (May 15, 2009); Exh. 114, Postings to http://finance.google.com/group/google.finance.660636/ (May 29, 2010).) Immediately after each interview, Hemispherx's Director of Investor Relations, Dianne Will, accessed the audio recording of the interview that Mr. Vlaicu had made available on his financial blog, StocksHaven.com. (*See* Exh. 112, Will Aff. ¶¶ 4, 6.) Hemispherx investors also were able to access and listen to the audio files of the interviews from StocksHaven.com. Indeed, at least one investor who listened to the May 29, 2009 audio file, posted his comments about the interview on the internet. (*See* Exh. 115, Michael Catalin Vlaicu, Hemispherx's Ampligen: Fact vs. Fiction, June 9, 2009, available at http://seekingalpha.com/article/141846-hemispherx-s-ampligen-fact-vs-fiction.) Since the May 2009 interviews, Mr. Vlaicu has removed his StocksHaven.com website and replaced it with a new website, TheMarketFinancial.com. (*See* 112, Will Affidavit ¶¶ 7-8.) Although Mr. Vlaicu's new website provides information about the May 15 and 29, 2009 interviews (Exh. 116, Postings of Michael Vlaicu to www.TheMarketFinancial.com (March 16, 2010)), the audio recordings of the interviews are not available on TheMarketFinancial website. In February 2010, Ms. Will obtained the audio recordings directly from Mr. Vlaicu, and provided a copy to defense counsel. (*See* Will Aff. ¶ 8.) Exhibit 119 was made from that copy of the recordings.

C. Defendants' Statements Of Belief, Forward-Looking Statements And Statements Of Optimism Are Not Actionable

1. Plaintiff Concedes That Several Of Defendants' Statements Of Belief, Forward-Looking Statements, And Statements Of Optimism Are Neither False Nor Misleading, And Its Claims Based On These Statements Must Be Dismissed

In its Opposition Brief, plaintiff states that "the following four statements were not alleged to be false and misleading by Plaintiffs:"

- "Yes. May 25, we would expect definitive response letters at that point."[14]
- "[W]e expect that sometime in the fall, perhaps sooner, we will be hearing from the – from the agency."[15]
- "[O]bviously, Holister-Stier [the manufacturing facility that received the 438 form] has an excellent reputation in this field, and we think that, ultimately, that will carry the day."[16]
- "I'm very pleased to say that the clinical inspections resulted in no findings which required corrective action by the Company, which I believe is a very unusual positive result. . . ."[17]

(Pl.'s Opp. Br. at 52.) Accordingly, all four statements must be stricken from the Amended Complaint, and all claims based on these statements must be dismissed with prejudice.

In addition, plaintiff concedes that the "statement cited by Defendants concerning no corrective action' following FDA inspections deals with Hemispherx's ability to manufacture Ampligen on a commercial level, and is not relevant to the allegations in the

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[14] Exh. 1, Am. Compl. ¶ 52; Exh. 73, 03/19/09 Conf. Call Tr. at 12;. *See*Defs.' Open. Br. Section IV.B.2 (explaining that this statement is also forward-looking and protected under the PSLRA safe harbor).

[15] Exh. 1, Am. Compl. ¶ 68; Exh. 74, 07/22/09 Conf. Call Tr. at 5. *See* Defs.' Open. Br. Section IV.B.2 (explaining that this statement is also forward-looking and protected under the PSLRA safe harbor)

[16] Exh 1, Am. Compl. ¶ 68; Exh 74, 07/22/09 Conf. Call Tr. at 10. *See* Defs.' Open. Br. Section IV.B.1 (explaining that this statement is also a non-actionable statement of belief.)

[17] Exh 1, Am. Compl. ¶ 71; Exh. 96, 10/09/09 Inter. Tr. at 8-9. *See* Defs.' Open. Br. Section IV.B.1 (explaining that this statement is also a non-actionable statement of belief.)

Complaint." (*Id.* at 53.) Thus, because plaintiff concedes that these statements are irrelevant, they cannot form the basis of plaintiff's claims and must be stricken from the Amended Complaint.

2. Defendants' Statements Of Belief And Opinion Regarding Ampligens®'s Prospects For FDA Approval Are Not Actionable Under Rule 10b-5

Plaintiff asserts that defendants' allegedly misleading statements "concern[] ***facts***, not opinions," in an attempt to make these statements appear actionable. (Pl.'s Opp. Br. at 44 (emphasis in original).) Specifically, plaintiff claims that defendants' statements "are capable of being proved literally true or false," and therefore are not opinion. (*Id.* at 44-45 (citing *Virginia Bankshares, Inc. v. Sandberg*, 501 U.S. 1083 (1991)).) Plaintiff then misleadingly quotes one of Dr. Carter's statements in an effort to show that it was literally false when made:

- Plaintiff's selective quotation:

> "We have answered all the major questions that have been put forward by the agency."

(Pl.'s Opp. Br. at 45.)

- Dr. Carter's actual statement:

> "We [Hemispherx] ***believe*** that we have answered all the ***major*** questions that have been put forward with the agency [FDA]."

(Defs.' Open. Br. (citing Exh. 1, Am. Compl. ¶ 52).) Plaintiff has alleged no facts showing that Dr. Carter did ***not*** believe this statement when he made it. Furthermore, Dr. Carter's conference calls and interviews often went on for pages and pages discussing highly specific statistics, medical terms, and testing protocols. Statements such as "[w]e believe that we have answered all the major questions that have been put forward with the agency" were the least factual thing Dr. Carter said in these interviews.

Plaintiff then attempts to bolster its argument that "[t]he majority of statements Defendants categorize as 'belief and opinion' can be confirmed as false" by citing two Hemispherx statements about changing FDA work priorities and Dr. Strayer's report on treadmill statistics. (Pl.'s Opp. Br. at 45 (citing Exh. 1, Am. Compl. ¶¶ 47, 49, 56).) The only problem for plaintiff is that ***defendants never categorized these statements as belief or opinion.*** Thus, plaintiff's attempt to show that defendants' statements concern facts and not opinions by misquoting defendants and citing statements defendants never contended were opinion in the first place demonstrates just how weak its position is on this issue.

Plaintiff next contends that defendants are taking snippets of allegedly false statements and quoting them without any context in an attempt to create a "strawman" argument. To the contrary, defendants are not creating a "strawman." Defendants have accurately quoted statements of opinion about their belief that no major questions remained outstanding with the FDA. Plaintiff contends that these statements of opinion were false because defendants had not addressed reports and clinical testing required by the FDA. Even without any context, it is clear that defendants' quotations of opinion are not "strawmen," but are directly responsive to and refute plaintiff's allegations of falsity.

In addition, plaintiff contends that defendants' statements "were ***shown*** to be false when Hemispherx issued its November 2, 2009 press release . . . ." (Pl.'s Opp. Br. at 46 (emphasis added).) Yet, as plaintiff itself points out, statements of opinion are only actionable "if ***known*** to be false." (*Id.* (citing *Hayes v. Gross*, 982 F.2d 104, 106 (3d Cir. 1992)) (emphasis added).) Plaintiff improperly conflates these two terms. The proper inquiry is whether a statement of opinion was ***known*** by the speaker to be false when made. *Hayes v. Gross*, 982 F.2d at 106 (opinion is only actionable where "defendant was aware that mismanagement had

occurred and made a material public statement about the state of corporate affairs inconsistent with the existence of the mismanagement"). Whether a statement of opinion is ***shown*** to be false through some later turn of events is irrelevant. Indeed, as defendants' Opening Brief points out, the Third Circuit has "'long rejected attempts to plead fraud by hindsight.'" (Defs.' Open. Br. at 70-71 (quoting *Cal. Pub. Employees' Ret. Sys., v. Chubb Corp.*, 394 F.3d 126, 158 (3d Cir. 2004)).)

Plaintiff also argues that defendants are being "disingenuous" by "suggesti[ing] that the investing public would not take Defendants at their word." (Pl.'s Opp. Br. at 46-47.) To the contrary, defendants make no such suggestion. In their Opening Brief, defendants suggest that "no reasonable investor would interpret Dr. Carter's repeated, consistent, and cautious expressions of opinion or belief on the status of the FDA's Ampligen review ***in the manner that plaintiff alleges.***" (Pl.'s Opp. Br. (citing Defs.' Open. Br. at 57) (emphasis added).) Defendants were merely suggesting that no reasonable investor would accept ***plaintiff's*** self-serving misinterpretation of Dr. Carter's statements. Defendants never suggested that no reasonable investor would not believe Dr. Carter himself. Indeed, plaintiff is piling misinterpretation upon misinterpretation by making such an argument in its Opposition Brief.

Finally, plaintiff claims that "even sophisticated securities ***analysts*** that followed and reported on Hemispherx were misled by Defendants' statements." (Pl.'s Opp. Br. at 47 (emphasis added).) Plaintiff is referring to Adam Feuerstein of *TheStreet.com*. Yet, *TheStreet.com*'s own website lists Mr. Feuerstein as a "columnist"- *i.e.*, a person who writes opinion- not one of its "analysts"- *i.e.*, a person who deals with financial facts. (Exh. 117, *TheStreet*.com, Masthead, *available at*, http://www.thestreet.com/static/about/masthead.html

last visited Mar. 30, 2010).)[18] More importantly, plaintiff's reference to Mr. Feuerstein is entirely irrelevant to the argument at hand that plaintiff's claims are based on inactionable opinion

In the end, none of plaintiff's flawed arguments demonstrate that defendant's statements were anything other than inactionable opinion. Plaintiff's claims based on these statements of opinion must be dismissed.

3. Plaintiff Has Failed To Demonstrate That Its Claims Can Escape The PSLRA's Safe Harbor

Plaintiff makes several flawed arguments to make the forward-looking statements contained in paragraphs 52, 68, and 69 of the Amended Complaint appear actionable. Plaintiff's contentions are contradicted by case law as well as the facts described in the Amended Complaint. Contrary to plaintiff's contentions, these forward-looking statements are properly protected by the PSLRA safe harbor. Accordingly, plaintiff's claims that rely on these forward-looking statements must be dismissed.

(a) The Challenged Statements Are Forward Looking

Plaintiff asserts that the statements contained in paragraphs 52, 68, and 69 of the Amended Complaint are not forward-looking. Plaintiff's argument, however, is based on distortions of both the governing law and the statements themselves. For instance, Plaintiff challenges Dr. Carter's statements from a July 22, 2009 Hemispherx investors conference call, in which Dr. Carter said: "[W]e ***expect*** that sometime in the fall, perhaps sooner, we will be hearing from the from the agency." (Exh. 1, Am. Compl. ¶ 68 (emphasis added); Exh. 74, 07/22/09

[18] In footnote 19 of its Opening Brief, plaintiff represents that TheStreet.com is a blog published on the *Wall Street Journal*'s website. It is not. *See* Exh. 118, The Wall Street Journal, WSJ Blogs, *available at*, http://blogs.wsj.com/?mod=WSJ_formfactor (last visited Mar. 30, 2010).

Conf. Call Tr. at 12. This statement discusses future events, and therefore, by necessity, it is forward-looking.

Further, plaintiff incorrectly relies upon several cases for the proposition that "[A] mixed present/future statement is not entitled to the safe harbor with respect to the part of the statement that refers to the present." (Pl.'s Opp. Br. at 48 n.31 (citing *Investors Group v. Avaya, Inc.*, 564 F.3d 242, 255 (3d Cir. 2009)); *see generally* Pl.'s Opp. Br. at 48-49 (citing cases).) In all of those cases, the challenged misstatements related to ***existing*** facts. For example, in *In re Cell Pathways, Inc. Sec. Litig.*, No. 99-752, 2000 U.S. Dist. LEXIS 8584, at *39-44 (E.D. Pa. June 21, 2000), the court refused to apply the safe harbor because "Plaintiffs have alleged that [Defendants] made material omissions of existing facts, i.e., flaws in the Phase III trial for [Defendant's pharmaceutical product]." Here, the statements at issue simply do not concern ***existing*** facts. Instead, plaintiff challenges defendants' projections about the ***future*** date expected for the FDA's Ampligen® NDA decision. Accordingly, *Avaya*, *Cell Pathways*, and the other cases plaintiff cites for this proposition are inapplicable. Indeed, persuasive case law actually weighs against plaintiff's position. *See Harris v. Ivax Corp.*, 182 F.3d 799, 806 (11th Cir. 1999) ("[W]ere we to banish from the safe harbor lists that contain both factual and forward looking factors, we would inhibit corporate officers from fully explaining their outlooks."); *In re Columbia Laboratories Inc. Sec. Litig.*, 144 F. Supp. 2d 1362, 1368 (S.D. Fla. 2001) ("Even statements that include both forward-looking and non-forward looking factors must be treated as forward-looking.").

(b) The Challenged Statements Fall Under The Safe Harbor's Well Defined Categories

Plaintiff also asserts that the challenged forward-looking statements are not protected by the safe harbor because, according to plaintiff, they do not fall into one of the safe

harbor's four well defined categories. (Pl.'s Opp. Br. at 49 (citing U.S.C.A. §78u-5(i)(1)(A), B), (C), (D)).) Specifically, plaintiff contends that "the Complaint does not allege that Defendants misled investors about their 'plans and objectives . . . for future operations,' such as, for example, whether Hemispherx intended to vigorously pursue the Ampligen NDA, or even whether Hemispherx intended to conduct additional Ampligen studies." (Pl.'s Opp. Br. at 49.) Contrary to Plaintiff's contentions, the Amended Complaint's facts show that Defendants' "plan[] and objective[]...for future operations" was to win FDA approval for Ampligen® so that the drug could be marketed commercially.[19] *See* 15 U.S.C.A. §78u-5(i)(1)(B) (protecting plans and objectives of management as well as plans and objectives related to products). The "assumptions underlying" this plan were that Hemispherx had submitted all necessary documentation and performed all necessary clinical testing to allow the FDA to make such a decision. *See id.* at §78u-5(i)(1)(D) (protecting assumptions underlying plans and objectives). Plaintiff in fact challenges the forward-looking statements containing these assumptions. (Exh. 1, Am. Compl. ¶¶ 52, 68, 69; *see generally id.*) Accordingly, the challenged forward-looking statements fall squarely within the categories of statements protected by the safe harbor.

(c) Hemispherx's Cautionary Language Is Specific And Warned Of The Very Risk That Came To Pass

Plaintiff also asserts an incorrect standard of review for the cautionary language accompanying forward-looking statements. Specifically, plaintiff asserts that "[t]he question of whether purportedly cautionary language identified by Defendants is sufficiently meaningful raises fact issues that are improperly resolved at the motion to dismiss phase." (Pl.'s Opp. Br. at 51 (internal quotations omitted).) Plaintiff cites only one case in support of this proposition, *In*

[19] Plaintiff does not, and cannot, challenge that Ampligen® is a "product" of Hemispherx. *See* 15 U.S.C.A. §78u-5(i)(1)(B) (protecting plans and objectives of management as well as plans and objectives related to products).

re Lucent Techs., Inc. Sec. Litig., 217 F. Supp. 2d 529, 557 (D.N.J. 2002). Plaintiff fails to mention, however, that in the only other opinion citing *Lucent*, the same District court later confined the *Lucent* holding to a more restrictive scenario where the adequacy of the warnings is not ***obvious*** to the court. *In re PDI Sec. Litig.*, 2005 U.S. Dist. LEXIS 18145, 37-38 (D.N.J. Aug. 16, 2005) (citing *Lucent*, 217 F. Supp. 2d at 557) (denying Defendant's Motion to Dismiss where "the adequacy of the warnings is not so obvious to this Court. . . ."). Contrary to plaintiff's assertion, Courts in this District routinely determine that cautionary language is sufficiently meaningful and then dismiss claims based on the accompanying forward-looking statements accordingly. *See, e.g., In re Nutrisystem Sec. Litig.*, 653 F. Supp. 2d 563, 579 (E.D. Pa. 2009); *In re Aetna, Inc. Secs. Litig.*, 2009 U.S. Dist. LEXIS 48910, at *72-75 (E.D. Pa. June 9, 2009); *In re Discovery Labs. Sec. Litig.*, 2007 U.S. Dist. LEXIS 18163, at *20-21 (E.D. Pa. Mar. 15, 2007). Indeed, the Third Circuit has consistently upheld the dismissal of claims predicated on forward-looking statements accompanied by meaningful cautionary language. *See Institutional Investors Group v. Avaya, Inc.*, 564 F.3d 242, 256-57 (3d Cir. 2009); *Key Equity Investors Inc. v. Sel-Leb Mktg.*, 246 Fed. Appx. 780, 786 n.8 (3d Cir. 2007); *GSC Partners CDO Fund v. Washington*, 368 F.3d 228, 242 (3d Cir. 2004).

Plaintiff also claims that defendant's two examples of cautionary language "are precisely the type of 'vague or blanket disclaimer' that does not qualify as meaningful cautionary language" under the PSLRA. (Pls.' Opp. Br. at 51.) Plaintiff's claim is nothing more than one sentence of pure *ipse dixit*. Furthermore, the only case plaintiff cites in support of this contention predates the PSLRA and analyzed the cautionary language in question under the "bespeaks caution" doctrine, not the statutory safe harbor that applies in the case at hand. (Pls.' Opp. Br. at 51 (citing *In re Donald J. Trump Casino Sec. Litig.*, 7 F.3d 357, 371-72 (3d Cir. 1993).)

Despite plaintiff's claims to the contrary, defendants' cautionary language was indeed specific and warned of the risk that ultimately came to pass. Plaintiff claims that defendants' forecasts regarding the timeframe for the FDA's Ampligen® NDA decision were false and misleading because these predictions did not take into account certain testing and documents the FDA requested in its Complete Response Letter that, according to plaintiff, were known to defendants during the putative Class Period. (*See* Defs.' Open. Br. at 60.) The ultimate risk associated with these allegedly misleading statements was that Hemispherx would fail to obtain regulatory approval for Ampligen® by a given PDUFA date. Yet plaintiff's Opposition Brief conveniently ellipses out the fact that Hemispherx's cautionary language indeed warned of that specific risk:

- Plaintiff's selective quotation:

> Ampligen may be found to be ineffective or to have adverse side effects, fail to receive necessary regulatory clearances, be difficult to manufacture on a commercial scale . . . We do not know when, if ever, Ampligen or our other products will be generally available for commercial sale . . . Generally only a small percentage of potential therapeutic products are eventually approved by the FDA for commercial sale.

(Pl.'s Open. Br. at 51.)

- Hemispherx's actual cautionary language:

> Ampligen® may be found to be ineffective or to have adverse side effects, fail to receive necessary regulatory clearances, be difficult to manufacture on a commercial scale, ***be uneconomical to market or be precluded from commercialization by proprietary right of third parties. Our products are in various stages of clinical and pre-clinical development and, require further clinical studies and appropriate regulatory approval processes before any such products can be marketed.*** We do not know when, if ever, Ampligen® or our other products will be generally available for commercial sale for any indication. Generally, only a small percentage of potential therapeutic products are eventually approved by the FDA for commercial sale.

(Exh. 8, 2008 Form 10-K at 14 (emphasis added).) The cautionary language directly warns about the very issues faced by Hemispherx- the need for additional clinical testing, and the possibility that Ampligen® might not be approved by a given PDUFA date, if ever.

(d) Plaintiff Fails to Allege Actual Knowledge

Finally, plaintiff has failed to allege the "actual knowledge" necessary to remove defendants' forward-looking statements from the protection of the safe harbor. *See Institutional Investors Group v. Avaya*, 564 F.3d 242, 274 (3d Cir. 2009) (recognizing that liability for forward-looking statements "attaches only upon proof of knowing falsity"); *In Re Discovery Labs. Sec. Litig.*, 2007 U.S. Dist. LEXIS 18163, at *4 (E.D. Pa. March 15, 2007) ("the burden is on plaintiffs to show that defendants ***knew*** the statement was false or misleading") (emphasis in original). As discussed *supra* and in defendants' Opening Brief, plaintiff's allegations fail to plead recklessness, much less actual knowledge. Accordingly, this Court should apply the safe harbor provision and dismiss all of plaintiffs' claims that are based upon the forward-looking statements contained in paragraphs 52, 68, and 69 of the Amended Complaint.

4. Several Of Defendants' Statements Of Belief And Forward-Looking Statements That Plaintiff Claims Violate Rule 10b-5 Also Constitute Immaterial Puffery And Are Non-Actionable For This Separate And Independent Reason

Plaintiff asserts an incorrect standard of review for vague and general statements of optimism and puffery to make the statements contained in paragraphs 52, 68, and 71 of the Amended Complaint appear actionable. Specifically, plaintiff asserts that "[m]ateriality determinations are generally not appropriate for a motion to dismiss . . . ." (Pl.'s Opp. Br. at 52.) Contrary to plaintiff's assertions, the Court need not conduct a fact based materiality analysis at the Motion to Dismiss stage because ***all*** vague and general statements of optimism and puffery, even if arguably misleading, are immaterial ***as a matter of law***. *In re Advanta Corp. Sec. Litig.*,

180 F.3d 525, 538 (3d Cir. 1999). In other words, once a statement can be characterized as a vague and general statement of optimism or puffery, then it is ***automatically*** deemed immaterial and, therefore, inactionable. As a result, courts in this District routinely dismiss claims based on optimism and puffery.[20] Indeed, the Third Circuit has consistently upheld the dismissal of claims predicated on vague and general statements of optimism and puffery. *See In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 538 (3d Cir. 1999) (statements touting quality of company's credit and expertise of company's management was puffery); *Shapiro v. UJB Fin. Corp.*, 964 F.2d 272, 283 n.12 (3d Cir. 1992) ("United Jersey looks to the future with great optimism" was non-actionable puffing).

Plaintiff also contends that "none of the statements Defendants categorize as puffery are 'general statements of optimism' or suggest an opinion, motive or intention of their speakers." (Pl.'s Opp. Br. at 53.) Plaintiff's contention is pure *ipse dixit* and is also contradicted by the very statements themselves. The four statements defendants identify as vague and general statements of optimism and puffery are as follows:

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[20] *See, e.g., In re Loewen Group Inc. Sec. Litig.*, No. 98-6740, 2003 U.S. Dist. LEXIS 15680, at *49 (E.D. Pa. July 16, 2003) ("[S]tatement[] that. . . company is. . . 'pursuing transactions on a selective and disciplined basis' [is] nothing more that [sic] corporate puffery. These are the kinds of positive statements that corporate officers make all of the time and that reasonable investors know to take with a grain of salt."); *In re Viropharma, Inc. Sec. Litig.*, No. 02-1627, 2003 U.S. Dist. LEXIS 5623, *21 (E.D. Pa. April 7, 2003) ("everybody is a potential patient," drug is "a scientific revolution," and a "very exciting product" "must be dismissed as mere puffing."); *In re U.S. Interactive, Inc. Class Action Sec. Litig.*, No. 01-CV-522, 2002 U.S. Dist. LEXIS 16009, at *21, 34 (E.D. Pa. Aug. 23, 2002) (statement that company was "only Internet professional services firm" with "marketing skills, expertise in wireless and broadband technologies" was non-actionable puffery.); *accord In re Syntex Corp. Sec. Litig.*, 95 F.3d 922, 933-34 (9th Cir. 1996) (dismissing statements regarding potential success of generic drug as "optimistic speculations"); *In re Milestone Scientific Sec. Litig.*, 103 F. Supp. 2d 425, 458, 462 (D.N.J. 2002) (phrases "very excited," "very pleased," "tremendous excitement," "very positive," and "revolutionize" are non-actionable puffery); *In re Cybershop.com Sec. Litig.*, 189 F. Supp. 2d 214, 232 (D.N.J. 2002) (defendant made "optimistic, possibly even ambitious, statements that are necessarily immaterial as a matter of law. . . even if they reflect 'misguided optimism'"); *In re Eng'g Animation Sec. Litig.*, 110 F. Supp. 2d 1183, 1195 (S.D. Iowa 2000) (phrases "strong financial condition," and "business prospects remain excellent" do not give rise to a securities violation because "[i]nvestors expect companies to think the best of themselves and predict growth"); *In re Cryomedical Scis., Inc. Sec. Litig.*, 884 F. Supp. 1001, 1020 (D. Md. 1995) ("hopeful statements" about medical device's "potential success" were non-actionable puffery).

- "Yes, May 25, we would **expect** definitive response letters at that point."[21]
- "[W]e **expect** that sometime in the fall, perhaps sooner, we will be hearing from the -- from the agency."[22]
- "Obviously, Holister-Stier [the manufacturing facility that received the 438 form] has an excellent reputation in this field, and **we think** that, ultimately, that will carry the day."[23]
- "I'm very pleased to say that the clinical inspections resulted in no findings which required corrective action by the Company, **which I believe is a very unusual positive result**."[24]

(Defs.' Open. Br. at 67-68 (emphasis added).) Plaintiff cannot credibly argue, for example, that the phrase "which I believe is a very unusual positive result," fails to communicate "optimism" or "suggest an opinion." Thus, plaintiffs' claims based on the statements in paragraphs 52, 68, and 71 of the Amended Complaint must be dismissed as mere puffery.[25]

III. CONCLUSION

For all of the above reasons, as well as the grounds set forth in defendants' Opening Brief, the Consolidated [Amended] Class Action Complaint should be dismissed with prejudice.

Respectfully submitted,

[21] Exh. 1, Am. Compl. ¶ 52; Exh. 73, 03/19/09 Conf. Call Tr. at 12. *See* Defs.' Open. Br. Section IV.C explaining that this statement is also forward-looking and protected under the PSLRA safe harbor).

[22] Exh. 1, Am. Compl. ¶ 68; Exh. 74, 07/22/09 Conf. Call Tr. at 12. *See* Defs.' Open. Br. Section IV.C explaining that this statement is also forward-looking and protected under the PSLRA safe harbor)

[23] Exh 1, Am. Compl. ¶ 68; Exh. 74, 07/22/09 Conf. Call Tr. at 10. *See* Defs.' Open. Br. Section IV.D explaining that this statement is also a non-actionable statement of belief.)

[24] Exh 1, Am. Compl. ¶ 71; Exh. 96, 10/09/09 Inter. Tr. at 8-9. *See* Defs.' Open. Br. Section IV.D explaining that this statement is also a non-actionable statement of belief.)

[25] In any event, as discussed *infra*, these statements are inactionable for the separate and independent reason that plaintiff has already conceded they are not false and are irrelevant.

/s/ Robert L. Hickok

Robert L. Hickok
Gay Parks Rainville
Michele C. Zarychta
William A. Liess
PEPPER HAMILTON LLP
3000 Two Logan Square
Eighteenth & Arch Streets
Philadelphia, PA 19103
(215) 981-4000

Attorneys for Defendants
Hemispherx Biopharma, Inc.
William A. Carter, M.D.
David R. Strayer, M.D.

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INDEX OF EXHIBITS

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111	U.S. Food and Drug Administration, June 21, 2007 Press Release, FDA Approves First Drug for Treating Fibromyalgia, *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2007/ucm108936.htm
112	Diane Will, April 1, 2010 Affidavit
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114	Postings to http://finance.google.com/group/google.finance.660636/ (May 29, 2010)
115	Michael Catalin Vlaicu, Hemispherx's Ampligen: Fact vs. Fiction, June 9, 2009, *available at* http://seekingalpha.com/article/141846-hemispherx-s-ampligen-fact-vs-fiction
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